

Mitchell E. Daniels, Jr. Governor

Judith A. Monroe, N.D. State Health Commissioner

DATE: April 11, 2008

TO: All Local Health Departments

Attn: Chief Food Inspection Officer

FROM: A. Scott Gilliam, MBA, CFSP

Manager, Food Protection Program

SUBJECT: Herbal Science International, Inc. Recalls Twelve Dietary Herbal Supplements

From the information provided by FDA, the recalled dietary supplements may present serious health hazard to consumers. The recalled products have been sold nationwide in herbal stores, and some may have been sold online directly to consumers. Information is being provided in case of consumer inquires.

Not classified; Herbal dietary supplements; Recommend notification of affected stores via phone, fax or e-mail.

Herbal Science International, Inc. Recalls Twelve Dietary Herbal Supplements Nationwide Because of Possible Health Risk Associated with Ephedra, Aristolochic Acid and Human Placenta

Contact: Ginger Chang (626) 333-9998

FOR IMMEDIATE RELEASE -- City of Industry, CA--April 10, 2007- Herbal Science International, Inc. (AKA Jen-On Herbal Science International, Inc.) is recalling twelve dietary supplements that contain ephedra, aristolochic acid or human placenta because they may present a serious health hazard to consumers.

FDA has long regarded dietary supplements containing ephedra as potential health hazards because this botanical contains ephedrine alkaloids. Ephedrine alkaloids are adrenaline-like stimulants that can have potentially dangerous effects on the heart. Recent studies have confirmed that ephedrine alkaloids raise blood pressure and otherwise stress the circulatory system, effects that are linked to adverse health effects like heart attacks and strokes. Based on this and other evidence in the scientific literature, FDA issued a rule in February 2004 prohibiting the sale of dietary supplements containing ephedrine alkaloids because they present an unreasonable risk of illness or injury. The company is recalling nine products that contain ephedra, a source of ephedrine alkaloids, as an ingredient sold labeled under the following brands:

Wu Yao Shun Qi San Qing Bi Tang (Nasal Cleanser) Zhong Fong Huo Luo Wan (Stroke Revito Formula) Xiao Qing Long Tang (Little Green Dragon) Ding Chuan Tang



Xiao Xu Ming Tang Feng Shi Zhi Tong Wan (Joint Relief) Guo Min Bi Yan Wan Fang Feng Tong Sheng San

Herbal Science International, Inc. is also recalling **Tou Tong San (Headache Formula)** and **Du Huo Ji Sheng Tang (Du Huo Joint Relief)**, two products containing aristolochic acid. Aristolochic acid is a potent carcinogen and nephrotoxin found in certain plants and botanicals. This chemical can cause serious kidney damage and the use of products that contain aristolochic acid has been associated with several occurrences of kidney failure. These products have also been linked to an increased risk of kidney cancer in people who have consumed them.

Finally, the company is recalling **Seng Jong Tzu Tong Tan**, a product that contains human placenta. Human placenta may transmit disease and dietary supplements that contain it may not be lawfully marketed in the United States.

All of the twelve products under voluntary recall are packed in white plastic bottles of 100 capsules. All lots are covered in this recall action. These products have been sold nationwide in herbal stores, by acupuncturists and on the internet.

Consumers who have purchased these products should immediately discontinue their use and return them to the place of purchase for a full refund. Consumers with questions may contact the company at (626) 333-9998. Consumers who have been taking the products and have experienced adverse reactions should consult their health care professional. Consumers and health care professionals can also report adverse events to the FDA's MedWatch program at 800-FDA-1088 or online at www.fda.gov/medwatch/report.htm.

No illnesses have been reported to the company to date in connection with these products and the company has ceased distribution of all of these products.

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Herbal Science International, Inc. apologizes for any inconvenience and expresses its concerns for the health of consumers by conducting a voluntary recall action. Herbal Science International, Inc. promises to ensure quality and integrity of all its products and the company is working closely with the FDA in the recall process.

